

Notice of Allowability

Application No.

10/687,188

Examiner

D. L. Jones

Applicant(s)

WEI, EDWARD T.

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/10/06.
2. ☒ The allowed claim(s) is/are 1-5, 7, and 11-15.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 10/26/06.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the after final amendment filed 10/10/06.

EXAMINER'S AMENDMENT

2. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Edward Wei on 10/26/06.

The application has been amended as follows.

Please replace the claims with the attached claim listing (on the following three pages).

1. **(Previously Presented):** A N-radiohaloaryl-alkylcarboxamide radioligand wherein the alkyl moiety thereof is a cyclohexane radical, the radioligand having a high affinity to TRP-M8 receptors in cells and tissues and having a specific activity of at least about 20 Ci/mmol or greater, wherein the TRP-M8 affinity is characterized by a K_d of about 1×10^{-5} or less.
2. **(Previously Presented):** The radioligand as in claim 1 wherein the radiohalo moiety is covalently bound in the molecule.
3. **(Previously Presented):** The radioligand as in claim 2 wherein the radiohalo moiety is selected from fluoride and iodide radionuclides.
4. **(Previously Presented):** The radioligand as in claim 3 wherein the specific activity is about 250 Ci/mmol or greater.
5. **(Previously Presented):** The radioligand as in claim 1 wherein the cyclohexane radical contains from 1 to 3 $C_1 - C_5$ normal or branched alkyl substituents.
6. **Cancelled.**
7. **(Previously Presented):** The radioligand as in claim 1 wherein the aryl moiety is a substituted aromatic radical represented by Y-, the substituents being

represented by R_1 , R_2 , and X, wherein

R_1 is selected from the group hydrogen, hydroxyl, $C_1 - C_3$ alkoxy, $C_1 - C_3$ carboxyalkyl, $C_1 - C_3$ oxycarbonylalkyl,

R_2 is selected from the group hydrogen, hydroxyl, $C_1 - C_3$ alkoxy, trifluoromethyl, nitro, cyano, halo, and

X is selected from the group [^{18}F]-, [^{123}I]-, [^{125}I]-, and [^{131}I]-.

8. Cancelled.

9. Cancelled.

10. Cancelled.

11. (Previously Presented): A composition comprising a N-radiohaloaryl-alkylcarboxamide of Formula 1:

Formula 1

R-CONH-Y

where (a) R is a cyclohexane radical containing from 1 to 3 $\text{C}_1 - \text{C}_5$ normal or branched alkyl substituents, and (b) Y is a substituted aromatic radical containing substituents R_1 , R_2 , and X, wherein

R_1 is selected from the group hydrogen, hydroxyl, $\text{C}_1 - \text{C}_3$ alkoxy, $\text{C}_1 - \text{C}_3$ carboxyalkyl, $\text{C}_1 - \text{C}_3$ oxycarbonylalkyl,

R_2 is selected from the group hydrogen, hydroxyl, $\text{C}_1 - \text{C}_3$ alkoxy, trifluoromethyl, nitro, cyano, halo, and

X is selected from the group [^{18}F]-, [^{123}I]-, [^{125}I]-, and [^{131}I]-.

12. (Previously Presented): The composition as in claim 11 wherein the cyclohexane radical of (a) contains 8-12 carbon atoms and the total number of carbon atoms in the alkyl substituents carbons are from 1 to 5.

13. (Previously Presented): The composition as in claim 12 wherein the carboxamide group is in an equatorial position relative to the plane of the cyclohexyl ring.

14. (Previously Presented): The composition as in claim 11 wherein the Formula 1 compound has a specific activity of about 20 Ci/mmol or greater.

15. (Previously Presented): The composition as in claim 11 wherein the Formula 1 compound is a ligand for the TRP-M8 receptor.

16. Cancelled.

17. - 22. Cancelled.

23. - 35. Cancelled.

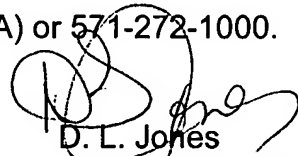
COMMENTS/NOTES

3. The claims are allowable over the prior art of record for reasons of record in the office action mailed 7/13/06.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


D. L. Jones
Primary Examiner
Art Unit 1618

October 26, 2006